

*REMARKS*

The Office Action dated February 15, 2008, and the references cited therein, have been considered. Claims 1-24 presently stand rejected under Section 112, paragraph 2 for failure to particularly point out the claimed invention. Claims 1-8 and 10-24 stand rejected as obvious over the combined teachings of the prior art. The Office Action states that Claim 9 would be allowable over the prior art if rewritten to include all the limitations of the base claim and any intervening claims. Applicants have amended the claims to improve their clarity and overcome the 35 U.S.C. 112 rejections. However, it is not necessary to amend the claims to overcome the obviousness rejections.

Applicants request favorable reconsideration of the grounds for rejection of the previously pending claims in view of Applicants' clarifying amendments to the claims and remarks addressing the shortcomings of the prior art with regard to particular recited elements of the claimed invention. Please charge any fee deficiencies to Deposit Account No. 12-1216.

*The Office Action's 35 U.S.C. 112 Rejections*

Applicants have amended the claims to address the Section 112, paragraph 2 rejections set forth in section 2 of the Office Action. Applicants amended claims 1 and 2 to eliminate "which." Applicants amended claims 2, 7, 12, and 14 to eliminate "practically." However, the present claim is intended to include "substantially continuous" and "substantially parallel" and "substantially fixed" embodiments – as such would be understood by those skilled in the art in view of Applicants' disclosed illustrative embodiments. Claim 12 is amended to change "*through* the heartbeat" to "*during* the heartbeat" to indicate that the artery is moving during the same time a heartbeat is occurring. Claim 12 is amended to change "this direction" to "the longitudinal direction" to indicate that the sensor is moving along a direction parallel to the longitudinal direction of the tissue's motion.

Applicants have amended claims 2 and 14 to remedy grammatical and idiomatic errors, and claim 10 is amended to remedy the absence of antecedent basis for "the motion."

*Summary of the Rejections in View of the Prior Art*

1. Claims 1-4, 6-8, 11, 13, 14, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp et al. US Pat. No. 6,099,471 (Torp) in view of Porat et al. US Pub. No. 2003/0220556 (Porat).

2. Claims 5, 10, 12, 15-17, 19, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torp in view of Porat and Panescu et al. US Pat. No. 5,848,969 (Panescu).

Applicants traverse the grounds for each and every rejection over the prior art for at least the reasons set forth herein below. Applicants address the specific rejections in the order they arise in the Office Action.

*Summary of Applicants' Disclosed/Claimed Invention*

Applicants' claimed invention is directed to a method and apparatus for generating hardness/elasticity information of tissue subject to a varying pressure as a sensor is drawn in a direction transverse to a measuring plane defined by the sensor. The exemplary embodiment discloses a three-dimensional imaging procedure/apparatus wherein an intravascular ultrasound transducer is withdrawn along a section of a blood vessel, subjected to varying pressure during a cardiac cycle, to render a three-dimensional representation of the hardness/elasticity of the vessel tissue. Moving the sensor along the tissue, in the case of a cardiac cycle, has the advantage of minimizing motion of an artery wall in particular circumstances described in paragraphs 0054 and 0055 of Applicants' published application. In particular, moving the sensor has the effect of fixing the sensor's position relative to the moving wall of the artery during a period within a cardiac cycle, thereby improving the quality of the palpogram. Thus, while moving the sensor along a vessel's length has the overall effect of providing an image of a length of a blood vessel, *in the short term* the movement of the sensor while acquiring ultrasound signal data within a portion of a cardiac cycle potentially minimizes the effect of an otherwise moving artery wall (in a transverse direction) during a single data acquisition period – such artery wall movement arising, for example, from blood pressure/flow variations during a heartbeat cycle.

*Rejection of Claims 1-4, 6-8, 11, 13, 14, 18, and 21-23 As Obvious Over Torp in view of Porat*

Applicants traverse the rejection, in section 6 of the Office Action, of claims 1-4, 6-8, 11, 13, 14, 18, and 21-23 as obvious over Torp in view of Porat. Applicants, as a general matter, traverse the “grounds for combining” the teachings of Torp and Porat set forth in the first full paragraph at the top of page 5 of the Office Action. The claimed invention is directed to a method (e.g., independent claim 1) and apparatus (e.g., independent claim 13). The Office Action states that the combination of Torp and Porat would facilitate determining a tissue parameter *along the length of tissue*. The claimed invention, clarified by the present invention, is directed to acquiring signal data while the sensor is moving in order to more closely track movement of tissue *as the signals are acquired by the sensor*. The claimed movement of the sensor has the effect of maintaining a same “field of view” for the sensor during the claimed signal acquisition step – not generating image data along the length of tissue. The movement of the sensor in the cited Porat reference is used to obtain image data for a new area of the imaged tissue. The combined teachings of Torp and Porat therefore neither disclose nor suggest Applicants’ claimed invention. The absence of specifically recited claim elements is addressed herein below.

*Independent Claims 1 and 13*

Torp does not disclose “relating the strain to at least one of either hardness or elasticity parameters of the tissue” as recited in claim 1. As recited in claim 1 and disclosed in the Application, “generating hardness information of the tissue” is a primary function of Applicants’ invention. *See*, Applicants’ specification, paragraph [0002]. Moreover, Torp does not disclose a method comprising among other things, “[i]dentifying strain of the tissue” as recited in claim 1. Rather Torp discloses a method and apparatus for determining *strain velocity*. *See* Torp, Abstract. That is, Torp measures the *rate of change in strain*, as distinct from strain. *See* Torp, col.1, ll.30-31. Given the differences between what Torp and Applicants seek to measure (i.e. strain velocity in Torp versus hardness and elasticity in the Application), Applicants submit that the combined teachings of Torp and Porat do not teach each of the recited elements of independent claims 1 and 13, and therefore the Office Action has not established a *prima facie* case of obviousness with regard to Applicants’ claimed

invention that recites using strain (identified from signals acquired by a transversely moving sensor) to determine hardness or elasticity parameters of the tissue.

Regarding the Office Action's assertions within the last paragraph of page 4, Applicants submit that Porat does not disclose a "sensor, where the sensor is moved during the receiving signals step: (a) in a direction transverse to the measuring plane, and (b) while the tissue is subject to a varying pressure" as recited in claim 1. The Office Action, citing paragraphs [0286] and [0298] of Porat, suggests Porat discloses a sensor which moves along the tissue in a direction transverse to the measuring plane. However, Porat, neither in these paragraphs or elsewhere in the patent, discloses this characteristic. Porat does not disclose the direction of its sensor's (which Porat patent refers to as "device 200") motion, or specifically whether the sensor's direction of motion is transverse to the measuring plane. Further, Porat does not disclose "the tissue is subject to a varying pressure" during a receiving signals or measuring step. A notable aspect of Applicants' disclosure is that the sensor conducts its measurements while the tissue is subject to a varying pressure, possibly as a result of the natural heartbeat. *See Applicants' specification, Paragraph [0056].*

Claim 13 is patentable over Torp and Porat for reasons similar to those discussed for claim 1. Unlike Applicants, Torp does not disclose an "apparatus for generating hardness information of tissue" as recited in claim 13. Rather Torp determines strain velocity using ultrasound. *See Torp, Abstract.* Further, Torp does not "relate the strain to elasticity and/or hardness parameters of a tissue surface." Nor does Torp disclose a "display device for displaying elasticity and/or hardness parameters of the tissue surface." In fact, Torp does not concern elasticity or hardness of tissue whatsoever. Porat, also unlike Applicants claimed apparatus, does not disclose "a sensor movable through a blood vessel or body cavity for recording signals . . . [sensor] being controllably moved along the tissue in a direction transverse to a measuring plane defined by the sensor" as recited in claim 13. Porat does not disclose the sensor's direction of movement, let alone that the sensor moves in a direction transverse to a measuring plane defined by the sensor. Additionally, Porat's sensor is not movable through a blood vessel or body cavity. Paragraphs [0096] and [0298] of Porat indicate that the sensor is placed on the "skin" of the body, preferably close to the "region-of-

interest.” The sensor is therefore, non-invasive and external to the body, and thus, cannot be movable through a blood vessel or body cavity.

*Dependent Claims 2-4, 6-8, 11, 14, 18, 21-23*

Dependent claims 2-4, 6-8, and 11, which depend upon independent claim 1, are patentable over Torp in view of Porat for at least the reasons set forth above with regard to claim 1. Further, with respect to claim 3, neither Torp nor Porat disclose the “step of displaying elasticity and/or hardness parameters of a tissue surface or tissue volume part.”

Dependent claims 14, 18, and 21-23, which depend upon independent claim 13, are patentable over Torp in view of Porat for at least the reasons set forth above with regard to claim 13. Further, with respect to claim 22, Porat does not disclose that its sensor is arranged in a catheter. Fig. 2c of Porat and accompanying descriptions disclose Porat’s sensor (device “200” in Fig. 2c of Porat) is not a catheter, since a catheter is a long narrow tube.

*Rejections of Claims 5, 10, 12, 15-17, 19, 20, and 24 Over Torp in view of Porat and Panescu.*

Applicants traverse the rejection, in section 7 of the Office Action, of claims 5, 10, 12, 15-17, 19, 20, and 24 as obvious over Torp in view of Porat, and in further view of Panescu. Claims 5, 10, and 12, which depend upon independent claim 1, are patentable over Torp in view of Porat, and in further view of Panescu for at least the reasons set forth above with respect to claim 1.

Further, with respect to claim 12, Panescu does not disclose that “the tissue is an artery moving during the heartbeat in the longitudinal direction, and the sensor is moved parallel to the longitudinal direction, so that, during at least one detection period, the sensor has a fixed position relative to the wall of the artery.” While Panescu’s sensor is movable, Panescu does not disclose that the tissue is also moving while the sensor is receiving signals. In addition, Panescu does not disclose that the sensor is moving along a direction parallel to the tissue’s direction of motion, such that the sensor has a fixed position relative to the tissue. According to Applicants’ disclosure, the elements recited in claim 12 provide improved recording of hardness and/or elasticity properties. *See* Application, Paragraphs [0018], [0055]. Claims 15-17, 19, 20, and 24, which depend upon independent claim 13, are

patentable over Torp in view of Porat and Panescu for at least the reasons set forth above with respect to claim 13.

*Claim 9 as Allowable*

Applicants acknowledge, with appreciation, the identification of claim 9 as allowable among the previously pending claims, if rewritten to overcome rejections under 35 U.S.C. 112, 2nd paragraph, previously set forth in the Office Action. In light of amendments to base claim 1, upon which claim 9 depends, claim 9 is sufficiently definite to overcome the previous 35 U.S.C. 112 rejection.

*Conclusion*

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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